

REMARKS

In the Office Action issued on September 19, 2007, the Examiner:

- objected to Claim 1 as reciting "a body vessel" where it should read "the body vessel";
- rejected claims 1, 2 and 8 under 35 U.S.C. §102(b) as being anticipated by Shaknovich (United States Patent No. 5,807,398);
- rejected claims 4 and 11 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of Kirkman (United States Patent No. 6,071,263);
- rejected claim 12 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of Pavcnik (United States Published Application No. 20010039450);
- rejected claims 13 and 14 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of Levine (United States Published Application No. 20040087965);
- rejected claim 18 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of Pavcnik.

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's objections and rejections. Reconsideration of the application for patent is requested.

Preliminary matter – Request for Continued Examination

The Applicants are filing this Reply and Amendment as the required submission for the Request for Continued Examination filed on even date herewith. Entry of this Reply and Amendment, and reconsideration of the application for patent, is therefore appropriate.

Objection to Claim 1

The Examiner objected to Claim 1 for reciting "a body vessel" where it should recite "the body vessel." The Applicants have herein amended Claim 1 to change "a" to "the" in line 9. This amendment is made simply to address the Examiner's objection and does not change the scope of protection sought.

The Applicants respectfully assert that this amendment fully overcomes the objection to Claim 1 and request its withdrawal.

Rejection of Claims 1, 2 and 8 under 35 U.S.C. §102

The Examiner rejected Claims 1, 2 and 8 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,807,398 to Shaknovich ("Shaknovich"). Specifically, the Examiner indicated that Shaknovich "discloses a method for delivering and deploying an expandable intraluminal device" that includes the steps recited in Claims 1, 2 and 8 of the present application for patent.

Shaknovich teaches a delivery system that is suitable for use in "pre-dilatation," a technique used in some stent deployments to pre-dilate an occluded portion of a vessel prior to deployment of the stent at the occlusion. According to Shaknovich:

"[t]he occluded region of the vessel may then be pre-dilated using the balloon catheter...**[t]hen**...the balloon may be deflated and advanced beyond (distal to) the occlusion. The balloon may **then** be pulled back into the deployment segment...and expanded to high pressures. Expanding the balloon accomplishes deployment of the stent...." (see column 4, lines 38-48).

This language from Shaknovich highlights the timing of steps in pre-dilatation techniques:

- First, a balloon is expanded to dilate a point of treatment in a body vessel
- Next, the balloon is deflated
- Next, the stent is advanced to and positioned at the dilated point of treatment
- Finally, the stent is deployed at the dilated point of treatment

Thus, stent dilatation of the point of treatment and stent deployment are two separate and distinct steps. To the extent that a portion of the delivery system is spaced from the vessel wall during dilatation, stent deployment does not occur while such spacing is occurring.

In contrast, deployment of an intraluminal medical device following the methods of the claimed invention occurs while the elongate member is being spaced from the vessel wall.

In order to more particularly point out and distinctly claim the invention, Claim 1 has been amended herein to explicitly require that the step of "deploying said expandable intraluminal medical device from the elongate member" occur "**while the elongate member is being spaced from a wall surface of the body vessel.**" This amendment is fully supported by the application as filed and does not introduce any new matter into the application. Exemplary support is

found in paragraphs [0043] and [0044], and also in Figures 5 and 6.

To the extent that the elongate member of Shaknovich is spaced from the vessel wall during the pre-dilation step, **Shaknovich does not teach or suggest the deployment of an expandable intraluminal medical device while the elongate member is being spaced from the wall surface.** As such, Shaknovich does not anticipate any of Claims 1, 2 or 8.

Applicants respectfully assert that the amendments made to Claim 1 fully overcome this rejection of the Claims and request its withdrawal.

Rejection of Claims 4 and 11 under 35 U.S.C. §103

The Examiner rejected Claims 4 and 11 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of United States Patent No. 5,807,398 to Kirkman ("Kirkman"). Specifically, the Examiner indicated that Shaknovich "discloses the claimed device except for the means for spacing comprising a basket formed from four wires having expanded and collapsed configurations and the step of activating the means for spacing includes retracting the sheath from a position about the means for spacing."

Both claims 4 and 11 depend from Claim 1 and, therefore, include all limitations of that claim. As described above, Claim 1 has been amended herein to require that the step of "deploying said expandable intraluminal medical device from the elongate member" occur "while the elongate member is being spaced from a wall surface of the body vessel."

Also as described above, Shaknovich does not teach or suggest the deployment of an expandable intraluminal medical device *while* the elongate member is being spaced from the wall surface. Kirkman fails to cure this defect of Shaknovich and, as such, the rejection does not present a *prima facie* case of obviousness because it fails to teach or suggest each and every limitation of the rejected claims.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 4 and 11 in light of the amendments made herein.

Rejection of Claim 12 under 35 U.S.C. §103

The Examiner rejected Claim 12 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of United States Published Application No. 20010039450 to Pavcnik ("Pavcnik"). Specifically, the Examiner indicated that Shaknovich "discloses the claimed steps except for the expandable intraluminal medical device comprising a venous valve."

Claim 12 depends from Claim 1 and, therefore, includes all limitations of that claim. As described above, Claim 1 has been amended herein to require that

the step of "deploying said expandable intraluminal medical device from the elongate member" occur "while the elongate member is being spaced from a wall surface of the body vessel."

Also as described above, Shaknovich does not teach or suggest the deployment of an expandable intraluminal medical device *while* the elongate member is being spaced from the wall surface. Pavcnik fails to cure this defect of Shaknovich and, as such, the rejection does not present a *prima facie* case of obviousness because it fails to teach or suggest each and every limitation of the rejected claim.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claim 12 in light of the amendment made herein.

Rejection of Claims 13 and 14 under 35 U.S.C. §103

The Examiner rejected Claim 14 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Published Application No. 20040087965 to Levine ("Levine"). The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claims 13 and 14 at least because the cited references do not teach or suggest all limitations of the rejected claim.

Claim 14 depends from Claim 13 and, therefore, includes all limitations of that claim. Kirkman fails to disclose the structural relationship between the elements that is required by Claim 13.

Claim 13 has been amended herein to require that "***the ancillary delivery device being movable within the lumen such that the basket can be distally advanced beyond the expandable intraluminal medical device.***" This amendment is fully supported by the application as filed and does not introduce any new matter into the application. Exemplary support is found in paragraphs [0041], and also in Figures 5 and 6.

Neither Kirkman nor Levine disclose an ancillary delivery device that meets this limitation of the rejected claims. Indeed, the structure relied on by the Examiner for the basket (element 104 of Levine) is incapable of being distally advanced beyond the expandable intraluminal medical device as it "define[s] a cage for containing the stent in a constricted form." (see paragraph [0009]). After deployment, "[t]he cage arms are opened and the stent is released." (see paragraph [0010]). The arms attach to the tubular portion, and are axially fixed in position relative to the tubular portion.

Thus, the rejection of Claims 13 and 14 does not present a *prima facie* case of obviousness because the asserted references fail to teach or suggest each and every limitation of the rejected claims.

Applicants respectfully assert that the rejection of Claims 13 and 14 is

improper and request its reconsideration.

Rejection of Claim 18 under 35 U.S.C. §103

The Examiner rejected Claim 18 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Published Application No. 20010039450 to Pavcnik ("Pavcnik").

Claim 18 depends from Claim 13 and, therefore, includes all limitations of that claim. As detailed above, Kirkman fails to disclose each and every limitation of Claim 13 as amended herein.

Pavcnik fails to cure the defect of Kirkman and, as a result, the combination of references does not disclose each and every element of the rejected claim. This flaw prevents the asserted combination of references from establishing a *prima facie* case of obviousness.

Applicants respectfully assert that the rejection of Claim 18 is improper and request its reconsideration.

CONCLUSION

The Applicants have fully responded to the rejections listed by the Examiner in the September 19, 2007 Office Action. Applicants respectfully assert that all pending claims define patentable subject matter and request reconsideration and issuance of an appropriate Notice of Allowability.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

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